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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,366	01/15/2004	David C. Gordon	64093-087	5297

7590 01/17/2007  
MCDERMOTT, WILL & EMERY  
Suite 3400  
2049 Century Park East  
Los Angeles, CA 90067

EXAMINER
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BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/758,366

Applicant(s)

GORDON ET AL.

Examiner

Mark W. Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                  |                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                             | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4-18-2005</u> | 6) <input type="checkbox"/> Other: ____                                                |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 25, 27, 33, 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudson et al. USPN 6,636,767. Knudson et al teach the introduction of a plurality of stimulators in various muscles (column 3, 55-64) in the oropharynx and using a pacing from and external controller 20 to contract the muscles to alleviate snoring.

Claims 23, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pitts US 2002/0049479. Pitts teach an implantable device that applies stimulation to the genioglossus muscle which has at least some minimal contraction [0021]. The device receives stimulation parameters telemetrically.

Claims 23, 25, 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Richmond et al. USPN 6,240,316.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitts US 2002/0048479 in view of Kallok USPN 5,158,080. Pitts describes the use of electrode arrays in which different protocols can be followed including phase shifting the stimulation. Though the references does not teach separate muscles be stimulating alternatively, in view of Kallock it would have been obvious to connect the individual electrodes to individual muscles of the and phase shift the stimulation to stimulate the muscles alternatively to reduce fatigue. Pitts uses sensors to initiate stimulation [0028], and with applicant's recited sensors being well known for detecting snoring such would have been obvious.

Claims 40, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond et al USPN 6,240,316. Richmond uses an injector for positioning the implant in the same location as applicant. It would have been apparent to one of ordinary skill in the art to use the same direction path as claimed to achieve the same result since it would have been one of the easier routes to take. To have tested the device prior to removal of the injector would have been obvious.

Claims 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond et al USPN 6,240,316 as applied to claims 40 above, and further in view of

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Pitts US 2002/0049479. Positioning the stimulator near any of the nerves feeding the genioglossus muscle as opposed to the muscle itself would have been an obvious alternative in view of Pitts.

Claims 24, 26, 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. USPN 6,636,767 in view of Richmond et al USPN 6,240,316. Applicant differs in reciting that the stimulator has two or more electrode and that the device is inserted using and injector device. To have inserted the Knudson et al stimulator with an injection device would have been obvious in view of Richmond et al as well as having provided multiple electrodes which Bion devices possess.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. USPN 6,636,767 in further in view of Li et al "Pharyngoscopic observation during sleep in patients with obstructive sleep apnea syndrome". Applicant differs from Knudsen et al in reciting that the patient's air passage in observed during sleep. Zhonghua teaches such a method for determining the location of blockages. To have used such a technique prior to installing the Knudsen device would have been obvious.

Claims 3-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. USPN 6,636,767 in further in view of Li et al "Pharyngoscopic observation during sleep in patients with obstructive sleep apnea syndrome" as applied to claims 3-22 above, and further in view of Richmond et al USPN 6,240,316. Applicant differs in reciting that the device is in an injector device with a stimulator and obvious parameters known to be included in Bion devices such as sensors and transmitters. The

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dependent claims represent old variations of techniques and tools that can be found in applicant's submitted IDS for treating OSA.

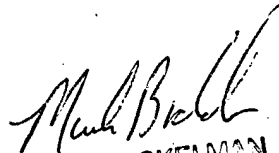
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

January 7, 2007

  
MARK BOCKELMAN  
PRIMARY EXAMINER